UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 15, 2017
Revised July 24, 2017

MEMORANDUM

Subject: Efficacy Review for Binary Ionization Technology (BIT) Plus,
EPA Reg. No. 90150-2;
DP Barcode #: 438832

From: Sophie Nguyen
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

To: John Hebert/Terria Northern
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: TOMI Environmental Solutions, Inc.
5111 Pegasus Court, Suite A
Frederick, MD 21704

Formulation from the Label:

Active ingredient:	% by Weight
Hydrogen peroxide	7.8
Other ingredients:	92.2
Total	100.0

I. BACKGROUND

The product, Binary Ionization Technology (BIT) Solution (EPA Reg. No. 90150-2), is an EPA-registered product designed as a healthcare-hospital disinfectant with bactericidal and virucidal activities. The applicant is submitting information to support a label amendment to add additional organisms to SteraMist Surface Unit Hand Held Device and SteraMist Environment System Room Fogging/Misting Device. The studies were conducted at Microchem Laboratory, 1304 W. Industrial Blvd, Round Rock, TX 78681.

The data package contained a letter to EPA (dated March 2, 2017), EPA form 8570-1 (Application for Pesticide Registration), EPA form 8570-34 (Certification with Respect to Citation Data), EPA Form 8570-35 (Data Matrix), 3 efficacy studies (MRID Nos. 50100801 - 50100803), and the proposed product label. Statement of No Data Confidentiality Claims, Good Laboratory Practice Statement, and Quality Assurance Statement were included with each study.

II. USE DIRECTIONS

The product, Binary Ionization Technology (BIT) Solution, is a microbial disinfectant fogging/misting solution for disinfection of all dry, pre-leaned, hard, non-porous, non-food contact surfaces in spaces and rooms. The product is designed to be used only with SteraMist application equipment such as SteraMist Environment System or SteraMist Surface Unit fogging/misting equipment following detailed instructions provided in the SteraMist Binary Ionization Technology (BIT) User Manual.

Binary Ionization Technology (BIT) Solution should be used as part of a Hospital Disinfectant Plan. In general, the SteraMist Surface Unit should be used when disinfecting (specific objects) ((and) (or)) (selected surfaces) with a directed mist from a distance of no more than two (2) feet. The SteraMist Environment System should be used when (all room surfaces) (the whole room) need(s) to be disinfected. For complete guidelines on developing a Hospital Disinfectant Plan/General Disinfectant Plan/Mold Remediation Plan, refer to the (attached) (Package Insert) (label) (insert) or equipment User Manual.

SteraMist™ Surface Unit Hand Held Fogging/Misting Directions:
Use the SteraMist™ Surface Unit exclusively in conjunction with the Binary Ionization Technology® (BIT™) Solution. For use in pre-cleaned enclosures and on pre-cleaned equipment. Remove any visible gross filth from surfaces and objects before application. The product must be used as packaged and not diluted in any way. To be used only on hard, non-porous surfaces.

For use on surfaces in industrial, commercial, and institutional settings (see label for list of specific Healthcare Use Sites and Other Use Sites lists). Apply at a maximum distance of 24 inches (2 feet) for a minimum of 5 seconds over a contiguous 1 square foot treatment area. Allow a minimum contact time of 7 minutes for the surface to dry. Refer to the attached Binary Ionization Technology® (BIT™) Solution (Package Insert) (label) for complete application instructions.

SteraMist™ Environment System Room Fogging/Misting Directions:
Use the SteraMist™ Environment System exclusively with Binary Ionization Technology® (BIT™) Solution. For use in pre-cleaned enclosures and on pre-cleaned equipment. Remove any visible gross filth from surfaces and equipment before application. The product must be used as packaged and not diluted in any way. To be used only on hard, non-porous surfaces.

For use in sealed rooms in industrial, commercial, and institutional settings (see label for list of specific Healthcare Use Sites and Other Use Sites lists). The use rate to achieve a minimum airborne concentration of 150 ppm (parts per million) hydrogen peroxide is approximately 0.5 milliliters (ml) of product per cubic foot (ft^3) of enclosure (room) volume. The application time needed to achieve the required concentration will vary depending upon the room size. Once the 150 ppm dose concentration is achieved, contact time must be maintained for a minimum of 15 minutes before initiating aeration of the room. Treatment area must remain unoccupied until a Drager, PortaSens or other monitoring device registers hydrogen peroxide levels at <0.2 ppm. Refer to the attached Binary Ionization Technology® (BIT™) Solution (Package Insert) (label) for complete application instructions.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

The Agency requires that specific disinfection claims for fogging/misting products and bio-decontamination systems intended for use on hard surfaces be supported by appropriate scientific data demonstrating the efficacy of the product and delivery system against the claimed test organism(s). Testing is accomplished in the laboratory by treating the test organism with the test substance under conditions which simulate as closely as possible the actual conditions under which the test substance is designed to be used. For fogging or misting bio-decontamination devices which is utilized as a disinfectant, efficacy testing is performed to determine that all exposed hard, non-porous surface within the enclosure are effectively treated with the disinfectant.

The fogging generation system used in the disinfection process will achieve the airborne test material concentration for the time period required for disinfection. The distribution of the fog will be assisted with fans. The system should be a completely self-contained bi-decontamination system with the ability to dehumidify, generate fog, and aerate sealed enclosures. Biological and chemical indicators will be equally distributed throughout the sealed enclosures to allow verification of treatment efficacy. After treatment, the aeration of the sealed enclosures will be performed until the test material is at an acceptable level. Safety monitoring for active ingredient diffusion into adjacent areas will be conducted during the test and in the sealed enclosure after completion of the disinfection process.

Disinfectants for Use on Hard Surface Environments (Additional Microorganisms):
Effectiveness of disinfectants against specific bacteria other than those named in the designated test microorganism(s) is permitted, provided that the target microbe is likely to be present in or on the recommended use areas and surfaces. This section addresses efficacy testing for limited, broad-spectrum or hospital disinfectants which bear label claims against bacteria other than *S. enterica* (ATCC10708), *S. aureus* (ATCC 6538) or *P. aeruginosa* (ATCC 15442). The effectiveness of disinfectant against specific bacteria must be determined by AOAC Use-Dilution Method (UDM). Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. The product should kill all the test microorganisms on all carriers in ≤ten minutes. The minimum carrier counts to make the test valid should be 1×10^4 CFU/carrier. For a valid test, no contamination of any carrier is allowed.

Virucides:
The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method

(for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Supplemental Claims:
An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same tolerance level.

IV. SYNOPSIS OF SUBMITTED EFFICACY STUDY

According to the Certificates of Analysis submitted with the studies, the tested concentrations for **Lot No. QE09A1, No. PL04A1, and No. PI15A2** were **7.4% Hydrogen peroxide**. The product's nominal concentration is 7.8% Hydrogen peroxide, and the Lower Certified Limit of the product is 7.41% Hydrogen peroxide.

1. **MRID 50100801 "Hard Surface Room Disinfection via a Fogging Device against *Salmonella*" Test Organisms: *Salmonella enterica* (ATCC 10708) for Binary Ionization Technology (BIT) Solution (EPA Reg. No. 90150-2), by Katelyn Hammond, Study conducted at Microchem Laboratory. Study completion date – Oct. 13, 2016. Study Identification No. GLP1505.**

This study was conducted against *Salmonella enterica* (ATCC 10708). Three batches (Nos. QE09A1, PL04A1, and PI15A2) of the product, Binary Ionization Technology (BIT) Solution, were tested using a Microchem Laboratory's modified protocol No. P1617 (copy provided). The batches of test substance were tested as a ready to use liquid with SteraMist Environmental System, Serial No. 302-2-110-0043. The solution was stored in ambient air temperature under fluorescent lighting. A daily test culture of the test organism was created from frozen stock culture in 10 mL of AOAC Synthetic Broth. It was incubated for 24±2 hours at 25-30°C. The cultures were initiated by performing daily transfers and incubated for 48-54 hours at 25-30°C. No organic soil load was used in the test culture. The test culture was vortex mixed for 3-4 seconds and allowed to stand for ≥10 minutes prior to use. The upper portion of the culture was removed and was pooled in a sterile vessel and mixed. Sixty (60) 18 x 36 x 1 mm glass slide carriers per product batch were each inoculated with 0.01 mL of culture over approximately 1 in^2 of each carrier. All inoculated carriers were dried for 30-40 minutes at 36±1°C and were used within 2 hours of drying. The carriers were placed at 20 locations, 3 per location. The sealed room measuring 19.90' x 14.55' x 12.67' (length x width x height), with a volume of approximately 3,668.5 ft^3 or 104 m^3 was used. All HVAC vents, exhaust ducts, etc. were sealed prior to test initiation. A humidifier was placed in the room to reach the desired humidity level. Hard, non-porous shelves capable of holding inoculated and dried

carriers at vertical and horizontal positions were placed on all walls and corners of the room. Inoculated and dried test carriers were placed in the test room at the following locations:

1. Lower right back corner at 0'
2. Lower right front corner at 0'
3. Lower left back corner at 0'
4. Lower front corner at 0'
5. Right wall center at 6'
6. Front wall center at 6'
7. Left wall center at 6'
8. Back wall center at 6'
9. Upper right back corner at 12'
10. Upper right wall center at 12'
11. Upper right front corner at 12'
12. Upper left back corner at 12'
13. Upper left wall center at 12'
14. Upper left front corner at 12'
15. Right wall center at 0'
16. Left wall center at 0'
17. Center room location at 0'
18. Center room location at 0'
19. Center room location under laboratory cart (horizontal) surface, approximately 4'
20. Center room location under laboratory cart (horizontal) surface, approximately 2'

Note: Final numbers control carriers were placed on top of the laboratory cart for each run.

Prior to exposure of carriers to test substance, active ingredient strips were placed around the vicinity of each carrier location. The device was then turned on and operated by the manufacturer's instructions. The door was immediately sealed, and the device was allowed to run for the application time of 25-28 minutes. The carriers were then allowed to sit, undisturbed for the contact time of 15-17 minutes at 24.0 – 24.5°C and in ≥50% relative humidity. The aeration time was 90-170 minutes. The total exposure time was 40-45 minutes. The total test cycle was 133 – 212 minutes. The room was deemed safe to entry when the air monitor read ≤0.2 ppm of active ingredient concentration within the test room. The carriers were aseptically and individually placed in tubes containing 20 mL of subculture/neutralization media (Modified Letheen Broth supplemented with 0.1% (w/w) sodium thiosulfate and 0.1% (v/v) catalase). Subculture/neutralizer tubes were incubated for approximately 46-47 hours at 35-37°C. After incubation, the number of test tubes showing growth was recorded along with the number of tubes not showing growth**.** Controls included those for initial and final numbers controls, viability, sterility, and purity controls, and neutralization control.

Note:

Protocol Amendments: No protocol amendment made to the protocol.

Protocol Deviations: 1) A deviation from the approved protocol occurred on 15 Aug 2016 wherein the aeration time was terminated prior to achieving the protocol specified active concentration of ≥0.2 ppm. The deviation occurred in an effort to prevent any loss of viability after both the Sponsor Company's Representative and the Study Director deemed the room safe to enter based on OSHA's exposure limit of 1.0 ppm per 8 hour period, and the limited time of potential exposure. The test room concentration reading was approximately 0.35 ppm according to the Sponsor-provided air monitor at the time of re-entry. This deviation was not thought to have an impact on the outcome of the study as the success criteria for all control carrier met that specified nu the protocol.

2) On 22 Aug 2016 a deviation from the approved protocol, P1617, occurred wherein the confirmatory streak plates for the control substance run were incubated for 73 hours and 31

minutes, however the protocol specifies all plates are incubated for 48±2 hours. The duration at which plates are incubated is important to achieve accurate plate counts when needed for enumeration. The purpose of these specific plates was simply to confirm observed presumptive positives (i.e., turbidity observed in test tubes) was in fact cause by growth of the test microorganism, not for enumeration purposes. Therefore, it is the decision of the Study Director that this deviation is not thought to have adversely affected the validity or accuracy of this study.

2. **MRID 50100802 "Hard Surface Room Disinfection via a Fogging Device against Feline Calicivirus" Test Organisms: Feline calicivirus, Strain F-9 (ATCC VR-782) for Binary Ionization Technology (BIT) Solution (EPA Reg. No. 90150-2), by Erika Guin, Study conducted at Microchem Laboratory. Study completion date – Oct. 13, 2016. Study Identification No. GLP1507.**

This study was conducted against Feline calicivirus, Strain F-9 (ATCC VR-782). Two batches (Nos. QE09A1 and PL04A1) of the product, Binary Ionization Technology (BIT) Solution, were tested using a Microchem Laboratory's modified protocol No. P1620 (copy provided). The batches of test substance were tested as a ready to use liquid with SteraMist Environmental System, Serial No. 302-2-110-0043. The solution was stored in ambient air temperature under fluorescent lighting. The F-9 strain of feline calicivirus was obtained from ATCC located in Manassas, VA. Prior to carrier inoculation, the test suspension was vortex mixed and diluted in sterile PBS to achieve the carrier counts. The host cell line was CRFK (ATCC CCL-94). No organic soil load was used in the test inoculum. Forty (40) 100 x 15 mm glass Petri dishes per product batch were each inoculated with 0.200 mL of inoculum volume over approximately 10-in^2 of each carrier. All inoculated carriers were dried for 26-47 minutes at 24.0 – 24.5°C. The carriers were placed at 20 locations, 2 per location. The sealed room measuring 19.90' x 14.55' x 12.67' (length x width x height), with a volume of approximately 3,668.5 ft^3 or 104 m^3 was used. All HVAC vents, exhaust ducts, etc. were sealed prior to test initiation. A humidifier was placed in the room to reach the desired humidity level. Hard, non-porous shelves capable of holding inoculated and dried carriers at vertical and horizontal positions were placed on all walls and corners of the room. Inoculated and dried test carriers were placed in the test room at the following locations:

1. Lower right back corner at 0'
2. Lower right front corner at 0'
3. Lower left back corner at 0'
4. Lower front corner at 0'
5. Right wall center at 6'
6. Front wall center at 6'
7. Left wall center at 6'
8. Back wall center at 6'
9. Upper right back corner at 12'
10. Upper right wall center at 12'
11. Upper right front corner at 12'
12. Upper left back corner at 12'
13. Upper left wall center at 12'
14. Upper left front corner at 12'
15. Right wall center at 0'
16. Left wall center at 0'
17. Center room location at 0'
18. Center room location at 0'

19. Center room location under laboratory cart (horizontal) surface, approximately 4'
20. Center room location under laboratory cart (horizontal) surface, approximately 2'

Prior to exposure of carriers to test substance, active ingredient strips were placed around the vicinity of each carrier location. The device was then turned on and operated by the manufacturer's instructions. The door was immediately sealed, and the device was allowed to run for the application time of 25-27 minutes. The carriers were then allowed to sit, undisturbed for the contact time of 15-16 minutes at 24.4 – 25.0°C and in ≥50% relative humidity. The aeration time was 92-170 minutes. The total exposure time was 40-42 minutes. The total test cycle was 133 – 212 minutes. The room was deemed safe to entry when the air monitor read ≤0.2 ppm of active ingredient concentration within the test room. The carriers were removed and exposed to 2.0 mL of neutralization media (10% FBS EMEM supplemented with 0.1% (w/w) sodium thiosulfate and 0.1% (v/v) catalase). Sterile cell scrapers were used to re-suspend the virus/test substance/neutralizer mixtures. The suspensions were considered the 10-1 dilution of the virus. Serial 10-fold dilutions were prepared to the necessary dilution and applied in quadruplicate per dilution to the host cell culture monolayers prepared to suitable confluency in multi-well trays for enumeration. The carriers were incubated for 7 days at 37±2°C, 5±1% CO_2. After incubation, the number of test tubes showing growth was recorded along with the number of tubes not showing growth**.** Controls included those for initial and final numbers controls, cytotoxicity, test substance neutralization, cell culture control, sterility, and virus stock titer control.

Note:

Protocol Amendments: No protocol amendment made to the protocol.

Protocol Deviations: 1) 15 Aug 2016: Aeration time was terminated prior to achieving the protocol specified active concentration of ≤0.2 ppm. The deviation occurred in an effort to prevent any loss of viability after both the Sponsor Company's Representative and the Study Director deemed the room safe to enter based on OSHA's exposure limit of 1.0 ppm per 8 hour period, and the limited time of potential exposure. The test room concentration reading was approximately 0.35 ppm according to the Sponsor-provided air monitor at the time of re-entry. This deviation was not thought to have an impact on the outcome of the study as the success criteria for all control carrier met that specified nu the protocol.

2) 17 Aug 2016: The control run of the test device was performed with initial plate recovery controls, in-room plate recovery controls, and final plate recovery controls performed in triplicate rather than singlet. Because this deviation provided additional information on the baseline titer of the test microorganism it is the determination of the Study Director that this deviation did not adversely impact the study outcome.

3) The protocol provides a calculation of the factor of the harvest volume as being: "Log10 [(Recovery Media Volume + Test Substance Volume)/Volume Plated Per Well]". While the accurate calculation is: "Log10 [(Recovery Media Volume + Test Substance Volume)/1.0 mL]. The accurate calculation was performed to provide the most correct assessment of viral titers for both test and control carriers. As such, it is the determination of the Study Director that this deviation does not adversely impact the study outcome.

MRID Nos. 50100801 & 50100802: According the TOMI Efficacy Technical Screen Deficiency Responses dated 5/16/17, the dose rate used in testing was approximately 0.5 mL/ft^3 or 150 ppb of Hydrogen peroxide. The fogger test equipment was operated by TOMI personnel during the testing.

3. **MRID 50100803 "GLP AOAC Germicidal Spray Products Test Modified for Handheld Spraying Device" Test Organisms: *Salmonella enterica* (ATCC 10708) for Binary Ionization Technology (BIT) Solution (EPA Reg. No. 90150-2), by Kelli**

Kuntzman, Study conducted at Microchem Laboratory. Study completion date – Sept. 12, 2016. Study Identification No. GLP1513.

This study was conducted against *Salmonella enterica* (ATCC 10708). Three batches (Nos. QE09A1, PL04A1, and PI15A2) of the product, Binary Ionization Technology (BIT) Solution, were tested using a Microchem Laboratory's modified protocol No. P1619 (copy provided). The batches of test substance were tested as a ready to use liquid spray. The spray bottle was the Handheld Spraying Device called SteraMist Surface Unit. A daily culture of the test organism was created by diluting the frozen stock in 10 mL of AOAC Synthetic broth. Subsequent daily transfers were performed, and from the daily culture, test cultures were initiated by transferring 0.010 mL into a sufficient number of tubes containing 10 mL of AOAC Synthetic broth. Test cultures were incubated at 36±1°C for 48-54 hours. The culture was not vortex mixed and allowed to stand for ≥10 minutes prior to use. The upper portion of the culture was removed and pooled into a sterile collection vessel. An organic soil load was not added to the culture. Sixty (60) 18 x 36 x 1 mm glass slide carriers per product batch were each inoculated with 0.010 mL of culture. The inoculum was spread uniformly over approximately 1 square inch, contained in the Petri dish. The carriers were dried for 30-40 minutes at 35-37°C. Dry carriers were horizontally oriented in the Petri dish and treated at intervals appropriate to ensure aseptic handling. The device was turned on and operated per instructions. The device was held so that the spray nozzle was approximately 18-20 inches above and directly in-line with the test surfaces. The device was moved slowly and steadily in a horizontal direction over the test surfaces for a total of 2 passes. After treatment, carriers were covered and left to sit for 7 minutes ± 5 seconds at ambient room temperature (~23°C). Following the exposure time, the medicated carriers were transferred to 20 mL of neutralization broth (Modified Letheen broth with 0.1% Sodium Thiosulfate and 0.01% Catalase). All subcultures were incubated for approximately 46 hours at 36±1°C. After incubation, the number of test tubes showing growth was recorded along with the number not showing growth, as indicated by the presence or absence of turbidity. If multiple tubes demonstrated growth, each of those tubes were confirmed not to be a result of contamination by plating on growth media. All confirmatory plates were incubated for 18-24 hours at 36±1°C. Controls included those of enumeration of inoculated test carriers, sterility, viability, neutralization, and purity.

Note:

Protocol Amendments: No protocol amendments were made for this study.

Protocol Deviations: 1) 22 Aug 2016: The neutralization verification inoculum for Binary Ionization Technology (BIT) Solution (Lot: QE09A1) was not between 10-100 CFU, but was instead higher than 100 CFU. This deviation was not thought to have an impact on the outcome of the study due to the results observed in 24AUG2016.

2) 23 Aug 2016: The neutralization verification inoculum for Binary Ionization Technology (BIT) Solution (Lots: PL04A1 & PI15A2) was not between 10-100 CFU, but was instead higher than 100 CFU. This deviation was not thought to have an impact on the outcome of the study due to the results observed in 25AUG2016.

V. RESULTS

Hard, Non-Porous Surface Disinfectant Applied Via SteraMist Environment System Fogging Device

Organism: *Salmonella enterica* (ATCC 10708), MRID No. 50100801

Airborne H_2O_2 Concentration Reached	Time	Bit Solution Lot No. (Test Date)	Temp. (RH)	No. of Carriers		Numbers Control-Geometric Mean (CFU/Carrier)
				No. Tested	No. Positive for Test Organisms	
0.5 mL/ft^3 or 150 ppb	AT: 25m + 37s CT: 15m + 3s AeT: 170m AT+CT+AeT = 210m	QE09A1 (15AUG2016)	24.4°C (50%)	60	0	6.89×10^5
	AT: 26m + 18s CT: 15m + 20s AeT: 92m AT+CT+AeT = 133m	PL04A1 (16AUG2016)	24.5°C (54%)	60	0	4.53×10^5
	AT: 27m + 37s CT: 17m + 45s AeT: 90m AT+CT+AeT = 134m	PI15A2 (16AUG2016)	24.5°C (55%)	60	0	6.43×10^5
	AT: 28m + 39s CT: 17m AeT: 90m	Control Substance (R/O Water) (17AUG2017)	24.0°C (59%)	10	10	1.25×10^6

MRID No. 50100802

Organism	Avg. Temp. (RH)	Time	Bit Solution Lot No. (Test Date)	Results		
				Description	Rep. 1 (Avg. 20 locations)	Rep. 2 (Avg. 20 locations)
Feline calicivirus Strain F-9 (ATCC VR-782)	34.65°C (73.8%)	AT: 25m + 37s CT: 15m + 3s AeT: 170m AT+CT+AeT = 210m	QE09A1 (15AUG2016)	Cytotoxicity	None observed	None observed
				Complete Inactivation	10^{-1} to 10^{-3} dilutions	10^{-1} to 10^{-2} dilutions
				$TCID_{50}$/1.00mL	$\leq 0.50 \log_{10}$	$\leq 0.50 \log_{10}$
				$TCID_{50}$/Carrier	$\leq 0.80 \log_{10}$	$\leq 0.80 \log_{10}$
				Final Recovery ($TCID_{50}$/1.00 ml)	**$5.00 \log_{10}$**	**$\geq 4.50 \log_{10}$**
				Final Recovery ($TCID_{50}$/Carrier)	**$5.30 \log_{10}$**	**$\geq 4.80 \log_{10}$**
	24.8°C (73.2%)	AT: 26m + 18s CT: 15m + 20s AeT: 92m AT+CT+AeT = 133m	PL04A1 (16AUG2016)	Cytotoxicity	None observed	None observed
				Complete Inactivation	10^{-1} to 10^{-2} dilutions	10^{-1} dilutions
				$TCID_{50}$/1.00mL	$\leq 0.50 \log_{10}$	$\leq 0.50 \log_{10}$
				$TCID_{50}$/Carrier	$\leq 0.80 \log_{10}$	$\leq 0.80 \log_{10}$
				Final Recovery ($TCID_{50}$/1.00 ml)	**$4.00 \log_{10}$**	**$\geq 3.50 \log_{10}$**

				Final Recovery (TCID$_{50}$/Carrier)	**4.30 log$_{10}$**	**≥3.80 log$_{10}$**
	24.0°C (75.3%)	AT: 28m + 39s CT: 17m AeT: 90m	Control Substance (sterile RO water) (17AUG2016)	**Description**	**Rep. 1 (Avg. 10 locations)**	
				Cytotoxicity	10^{-1} to 10^{-5}	
				Complete Inactivation	No	
				TCID$_{50}$/1.00mL	3.50 – 4.50 log$_{10}$	
				TCID$_{50}$/Carrier	3.80 – 4.80 log$_{10}$	
				Final Recovery	**Rep. 1**	**Rep. 2**	**Rep. 3**
				(TCID$_{50}$/1.00 ml)	**5.00 log$_{10}$**	**5.25 log$_{10}$**	**4.50 log$_{10}$**
				(TCID$_{50}$/Carrier)	**5.30 log$_{10}$**	**5.55 log$_{10}$**	**4.80 log$_{10}$**

AT: Application Time
CT: Contact Time
AeT: Aeration Time

Hard, Non-Porous Surface Disinfectant Applied Via SteraMist Surface Unit Hand Held Device

Contact Time	**MRID No.**	**Organism**	**Batch No.**	**Results**		**Carrier Population (log$_{10}$ CFU/Carrier)**
				No. Carriers Exhibiting Growth/Total Carriers	No. of Confirmed Positive	
7 minutes ± 5 seconds	50100803	*Salmonella enterica* (ATCC 10708)	QE09A1 (22AUG2016)	1/60	0	5.11
			PL04A1 (23AUG2016)	*2/60	0	5.57
			PI15A2 (23AUG2016)	0/60	0	5.42

***Note:** The Agency's current policy allows for contamination of only one carrier per 60-carrier set, and occurrence of more than one contaminated carrier invalidates the test results. However, because efficacy data were approved for the other two base organisms (i.e., *S. aureus* and *P. aeruginosa*) for this use, *Salmonella enterica* will be considered an additional organism. Therefore, efficacy consideration for the organism will be based on the other two batches. [Source: Agency's 810.2200 Disinfectants for Use on Hard Surfaces testing guidance]

VI. CONCLUSION

1. The following submitted efficacy data **support** the use of the product, Binary Ionization Technology (BIT) Solution (EPA Reg. No. 90150-2), as a disinfectant to be applied by fogging via SteraMist Environment System Fogging Device, with bactericidal and virucidal activities against the following microorganisms with precleaning instructions on hard, non-porous surfaces:

MRID	Organisms
50100801	*Salmonella enterica* (ATCC 10708)
50100802	Feline calicivirus Strain F-9 (ATCC VR-782)

The test data submitted did not take into account the room size when determining the number of test carriers. The formula below should be used to determine the required number of test carriers:

[(m^3 – 10) / 2] + 15, where m^3 is the cubic meter area of the sealed enclosure. Note that this equation is only applicable to enclosures ≥60 m^3.

In addition, the test data did not specify the orientations of the carriers at each location. Three orientations are required to be tested for each location.

7/24/17: A decision was reached to allow the above claims on the label. TOMI argued that the product was accepted previously using efficacy data against the organisms, *Staphylococcus aureus (S. aureus)*, *Pseudomonas aeruginosa (P. aeruginosa)*, and *Clostridium difficile*, tested under acceptable testing method and conditions. According to TOMI, "thus, over the course of these two studies, 438 carriers were successfully inoculated and treated, with passing results for each lot." Furthermore, "TOMI asserts that the results of these most recent studies should be sufficient to support efficacy claims for efficacy against the additional organisms *Salmonella enterica*, ATCC 10708 (*S. enterica*), and Feline calicivirus (Norovirus), ATCC VR-782."

The Agency also receives a letter from Microchem Lab (dated 7/14/17), assuring the Agency of the product's efficacious nature against the above organisms using the fogger/mister application. Concerning the carrier number, Microchem Lab assures that "The choice to use 60 carriers for Salmonella was based on past successful fogger efficacy submissions for other clients. Microchem recognizes that the carrier number expectation has now changed within EPA and will use EPA's formula for carrier number calculation going forward." Furthermore, "Microchem also notes that TOMI conducted a C. difficile study prior to our work with TOMI that was accepted by EPA.

"That particular recent EPA-accepted protocol was shared with Microchem by TOMI prior to the feline calicivirus and Salmonella tests and was used by Microchem to confirm current EPA preferences for fogger studies. Microchem believes that feline calicivirus, as an additional organism, should be treated similarly to C. difficile, with carrier-up data being sufficient. Microchem believes that existing P. aeruginosa data, which included carriers in different orientations, should address any lingering concerns EPA has about Salmonella efficacy in light of our studies."

2. The submitted efficacy data **supports** the use of the product, Binary Ionization Technology (BIT) Solution (EPA Reg. No. 90150-2), as a spray disinfectant when applied via SteraMist Surface Unit Hand Held Device at a distance of 18-20 inches from applicator to surfaces, with bactericidal activity against the following organism for a 7-minute contact time with precleaning instructions on hard, non-porous surfaces:

MRID	Organisms
50100803	*Salmonella enterica* (ATCC 10708)

Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization effectiveness control showed positive

growth of the microorganisms. The challenge microorganism was confirmed by wet mount and colony morphology. Viability controls were positive for growth. Sterility controls did not show growth.

VII. LABEL RECOMMENDATIONS (for proposed label dated 07/21/17)

1. The proposed label claims are acceptable regarding the use of the product, Binary Ionization Technology (BIT) Solution (EPA Reg. No. 90150-2), as a disinfectant against the following organisms when applied via fogging using SteraMist Environment System Fogging Device for use on hard non-porous surfaces:

   Salmonella enterica (ATCC 10708)
   Feline calicivirus Strain F-9 (ATCC VR-782)

   7/24/17: These claims are supported by the applicant's data based on the rationale provided by TOMI and Microchem Laboratory.

2. The proposed label claims are acceptable regarding the use of the product, Binary Ionization Technology (BIT) Solution (EPA Reg. No. 90150-2), as a disinfectant when applied as a spray via SteraMist Surface Unit Hand Held Device for use on hard non-porous surfaces with precleaning instructions at a distance of 18-20 inches (no more than 1.67 feet) against the following organisms:

   Salmonella enterica (ATCC 10708)

   These claims **are supported** by the applicant's data.

3. The proposed language to label the SteraMist Surface Unit as a direct fogger/mister that produces a direct mist/fog onto surfaces is not acceptable. The Agency reserves the fogging/misting application label claims to only applications that were tested using the appropriate protocol and conditions. To label the SteraMist Surface Unit as a fogger/mister or fogging/misting application would be misleading, since this handheld unit device was only tested as a sprayer. Therefore, registrant should remove all fogging/misting claims (or references) associated with this application device.

4. On page 4, pre-cleaning instructions for *C. diff* spores should include detailed instructions outlined in the *C. diff* guidance. Instructions to pre-clean surfaces and whole room may not need to utilize the same device/application. The label may instruct users to use a different sporicidal product with liquid application.

5. On page 8, remove “works” from the claims “Aerosolized application (works) (spreads) like a gas” for Surface Unit Claims.

6. On page 10 of the proposed label, remove the claim “Application equipment is easily manipulated to apply fog/mist (behind objects) (and)/(or) (around corners) (and)/(or) (in difficult to treat areas)” from the Surface Unit Claims Only section. Thus claim implies that

the handheld unit device is a whole room fogger/mister, a term that the Agency reserves for products that have been approved as a room fogger/mister.

7. On page 11, remove “Effective for use against (mold) (and) (mildew) for aesthetic purposes only”. The claim “Effective for use against…” implies killing and disinfecting of mold and mildew.